Remarks

Introduction

Claims 25-38 were pending. By way of this response, the specification has been amended, claims 25-38 have been cancelled without prejudice, and claims 39-48 have been added. The specification has been amended to correct various inadvertent typographical errors. Support for the amendments to the specification and new claims can be found in the application as originally filed (e.g., including examples 41-45), and care has been taken to avoid adding new matter. Accordingly, claims 39-48 are currently pending.

Claims 39-48 are similar in wording to issued claims 1-10 of U.S. Patent No. 5,919,665, except the present claims are directed to fusion proteins and host cells which comprise at least a portion of botulinum toxin type E.

Double Patenting

Claims 25-26 have been rejected under the judicially created doctrine of obviousness type double patenting over claims 1 and 2 of U.S. Patent No. 5,919,665.

Applicant does not concede the correctness of the rejections. However, to advance the prosecution of the above-identified application, claims 25-25 have been cancelled, and claims 39-48 have been added. Applicant submits that the subject matter of present claims 39-48 is not obvious over claims 1 and 2 of U.S. Patent No. 5,919,665 since the claims are

directed to proteins which comprise portions of different botulinum toxins, and host cells comprising portions of different botulinum toxins.

In view of the above, applicant submits the double patenting rejection has been overcome and respectfully requests withdrawal of the rejection.

Claim Objections

Claims 25-38 have been objected because claim 28 recites "wherein the toxin is in solution", and claims 25-38 recites the phrase "comprise SEQ ID NO:28".

As indicated above, claims 25-38 have been cancelled. Applicant submits that the present claims, that is claims 39-48, do not include the objected language, and are definite.

In view of the above, applicant submits the claim objections have been overcome and respectfully requests withdrawal of the objections.

Rejection Under 35 U.S.C. § 102

Claims 25-38 have been rejected under 35 U.S.C. § 102(e) as being anticipated by Dolly et al. (U.S. Pat. No. 6,203,794) as evidenced by Ledoux (1994).

Applicant traverses the rejections as it relates to the present claims.

Applicant submits that Dolly does not specifically disclose, teach, or suggest the present invention. For example, Dolly does not specifically disclose, teach, or even suggest a soluble fusion protein comprising a non-toxin protein sequence and at least a portion of the Clostridium botulinum type E toxin, let alone such a soluble fusion protein wherein the portion of the Clostridium botulinum type E toxin is selected from the group consisting of SEQ ID NO:50 and SEQ ID NO:52, as recited in claim 39. Dolly also does not specifically disclose a host cell containing a recombinant expression vector that encodes a protein that comprises at least a portion of a Clostridium botulinum type E toxin protein sequence selected from the group consisting of SEQ ID NO:50 and SEQ ID NO:52, let alone, such a host cell which is capable of expressing the protein at a level greater than or equal to 0.75% of the total cellular protein, as recited in claim 44. Further, Dolly does not specifically disclose, teach, or even suggest a soluble fusion protein that comprises at least a portion of Clostridium botulinum C fragment of a Clostridium botulinum type E toxin linked to a poly-histidine tag, as recited in claim 48.

In contrast to the present claims, Dolly discloses a recombinantly produced botulinum toxin type A light chain coupled to a native botulinum toxin type A heavy chain (i.e., a botulinum toxin heavy chain obtained from anaerobic Clostridium botulinum bacteria) (e.g., see examples 11-22).

Dolly does not specifically disclose, teach, or even suggest fusion proteins and host cells which comprise at least a portion of a Clostridium botulinum type E toxin, as recited in the present claims.

Since Dolly does not specifically disclose each and every element recited in the present claims, applicant submits that Dolly does not anticipate the present claims under 35 U.S.C. § 102.

In addition, applicant submits that the present claims are unobvious from and patentable over Dolly under 35 U.S.C. § 103 since Dolly specifically discloses botulinum toxin type A-based molecules, and since Dolly does not provide any amino acid sequence information for botulinum toxin type E based molecules, which such sequence information is recited in the present claims.

In view of the above, applicant submits that the present claims, that is claims 39-48, are not anticipated by, and are unobvious from and patentable over, Dolly under 35 U.S.C. §§ 102 and 103.

In addition, each of the present dependent claims is separately patentable over the prior art. For example, none of the prior art disclose, teach, or even suggest the present fusion proteins and host cells including the additional feature or features recited in any of the present dependent claims. Therefore, applicant submits that each of the present claims is separately patentable over the prior art.

Conclusion

In conclusion, applicant has shown that the present claims are not subject to obviousness type double patenting, are in

proper form, and are not anticipated by and are unobvious from and patentable over the prior art under 35 U.S.C. §§ 102 and 103. Therefore, applicant submits that the present claims are allowable, and respectfully requests the Examiner to pass the above-identified application to issuance at an early date. Should any matters remain unresolved, the Examiner is requested to call (collect) applicant's attorney at the telephone number given below before mailing another Office Action.

Date: 6/10/05

Respectfully submitted,

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